



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 68

[Docket No. NIH-2020-0001]

RIN 0925-AA68

National Institutes of Health Loan Repayment Programs

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS or Department), through the National Institutes of Health (NIH), proposes to update the existing regulation for NIH Loan Repayment Programs (LRPs) to reflect the consolidation of NIH LRPs into two programs, the Intramural Loan Repayment Program (for NIH researchers) and the Extramural Loan Repayment Program (for non-NIH researchers); the direct authority of the NIH Director to administer the NIH LRPs (formerly the duty of the Secretary, HHS); and the increase in the annual loan repayment amount from a maximum of \$35,000 to a maximum of \$50,000.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may send comments, identified by Docket Number NIH-2020-0001 and/or RIN 0925-AA43, by any of the following methods:

Electronic Submissions:

You may send comments electronically in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov/>. Follow the instructions for sending comments.

Written Submissions:

You may send written comments in the following ways:

Please allow enough time for mailed comments to be received before the close of the comment

period.

- Mail (for paper or CD-ROM submissions): Daniel Hernandez, NIH Regulations Officer, National Institutes of Health, Office of Management Assessment, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601-T, MSC 7901, Bethesda, Maryland 20892-7901.
- Hand delivery/courier (for paper or CD-ROM submissions): Daniel Hernandez, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601-T, MSC 7901, Bethesda, Maryland 20892-7901.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments will be posted without change to <https://www.regulations.gov/>, including any personal information provided.

Docket:

For access to the docket to read background documents or comments received, go to the eRulemaking Portal at <https://www.regulations.gov/> and insert the docket number provided in brackets in the heading on page one of this document into the: “Search” box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Daniel Hernandez, NIH Regulations Officer, Office of Management Assessment, NIH, Rockledge 1, 6705 Rockledge Drive, Suite 601, Room 601-T, MSC 7901, Bethesda, Maryland 20892-7901, by email dhernandez@od.nih.gov, or by telephone 301-435-3343 (not a toll-free number) for information about the rulemaking process.

For program information contact: Matthew Lockhart, NIH Division of Loan Repayment, by email matthew.lockhart@nih.gov, or telephone 866-849-4047. Information regarding the requirements, application deadline dates, and an on-line application for the NIH Loan Repayment Programs may be obtained from the NIH Loan Repayment Program website <https://www.lrp.nih.gov/>.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The purpose of the NIH LRP programs is to recruit and retain highly qualified health professionals as biomedical and behavioral researchers. The programs offer educational loan repayment for participants who agree, by written contract, to engage in qualifying domestic non-profit supported research at a qualifying non-NIH institution, or as an NIH employee for a minimum of two years (or three years for the Intramural LRP's general research subcategory).

On December 13, 2016, Congress enacted the 21st Century Cures Act, Public Law (Pub. L.) 114-255, Section 2022 of which amended the Public Health Service (PHS) Act to authorize the consolidation of National Institutes of Health Loan Repayment Programs (LRPs) into the Intramural Loan Repayment Program and the Extramural Loan Repayment Program.

The legislation also provides the NIH Director with the authority to establish or eliminate one or more subcategories of the LRPs to reflect workforce or scientific needs related to biomedical research. Thus, this statute allows for up to four subcategories for the Intramural Loan Repayment Program (General, Acquired Immunodeficiency Syndrome (AIDS), Clinical for Researchers from Disadvantaged Backgrounds, and one additional subcategory) and up to six subcategories for the Extramural Loan Repayment Program (Contraception & Infertility, Pediatric, Clinical, Health Disparities, Clinical for Researchers from Disadvantaged Backgrounds, and one additional subcategory).

Furthermore, the 21st Century Cures Act provides the NIH Director with direct authority to administer the NIH Loan Repayment Programs (formerly the duty of the Secretary, HHS).

Finally, the legislation authorizes NIH to raise its annual loan repayment amount to a maximum of \$50,000, which reflects a change from the previous maximum annual loan repayment amount of \$35,000.

The PHS Act, as amended, now contains sections 487A (Intramural loan repayment program;

42 U.S.C. 288-1) and 487B (Extramural loan repayment program; 42 U.S.C. 288-2), with the removal of previous sections 464z-5, 487C, 487E, and 487F by the 21st Century Cures Act. Sections 487A and 487B of the PHS Act authorize the NIH Director to enter into contracts with qualified health professionals under which such professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such service, not more than \$50,000 of the principal and interest of the qualified educational loans of such professionals. In return for these loan repayments, applicants must agree to participate in qualifying research for an initial period of not less than two years (or a minimum of three years for the Intramural LRP's general research subcategory), as one of the following: (1) An NIH employee (for Intramural LRP), or (2) A health professional engaged in qualifying research supported by a domestic non-profit foundation, non-profit professional association, or other non-profit institution (e.g., university), or a U.S. or other government agency (Federal, State or local).

II. Summary of Proposed Changes

With this notice of proposed rulemaking (NPRM), we propose to update the existing regulation for NIH LRPs codified at 42 CFR Part 68, and titled National Institutes of Health Loan Repayment Programs, to reflect the changes in NIH LRPs that resulted from enactment of the 21st Century Cures Act.

Specifically, we propose to amend the authority citation by adding the United States Code (U.S.C.) citation 42 U.S.C. 216 and removing U.S.C. citations 42 U.S.C. 254o, 42 U.S. C288-3, 42 U.S.C.288-5, 42 U.S. C. 288-5a, 42 U.S.C. 288-6, and 42 U.S.C.285t-2.

We propose to amend § 68.1 by removing the references to sections 487C, 487E, 487F and 464z-5 of the Public Health Service Act (PHS Act), and references to U.S.C. citations 42 U.S.C.288-3, 42 U.S.C. 288-5, 42 U.S.C. 288-5a, 42 U.S.C. 288-6, and 42 U.S.C. 285t-2; and by

revising the last sentence of the introductory narrative to indicate that the NIH Loan Repayment Programs include two separate programs, the Intramural Loan Repayment Program (for NIH researchers) and the Extramural Loan Repayment Program (for non-NIH researchers).

Additionally, we propose to amend paragraphs (a) and (b) by revising them and their respective subparagraphs in their entirety to reflect that there are currently two NIH LRPs, the Intramural LRP with up to four subcategories and the Extramural LRP with up to six subcategories.

We propose to amend § 68.2 by removing the term “Secretary,” adding the term “Research in Emerging Areas Critical to Human Health,” and revising the term “Nonprofit funding/support to read “Nonprofit research funding/support.” We further propose to amend § 68.2 by revising the definitions for “Debt threshold,” “Director,” “Educational expenses,” “Extramural LRPs,” “Intramural LRP,” “Loan repayment programs,” “Participant,” “Program eligibility date,” “Qualified Educational Loans and Interest/Debt,” “Reasonable educational and living expenses,” “Repayable debt,” and “Waiver.”

We propose to amend § 68.5 by revising paragraph (d) to state that for Extramural LRPs only, individuals who receive any salary support or participate in research that receives funding support from a for-profit institution or organization, or Federal Government employees working more than 20 hours per week are ineligible to participate.

We propose to amend § 68.6 by removing the word “Secretary” and adding in its place the words “NIH Director.”

We propose to amend § 68.7 by revising paragraph (d)(2)(iii) to state that for the minority health disparities subcategory, at least 50 percent of the contracts are required by statute to be for appropriately qualified health professionals who are members of a health disparity population.

We propose to amend § 68.8 by revising paragraph (a) to state that NIH may pay up to \$50,000 per year of a participant’s repayable debt rather than the previous \$35,000 per year.

We propose to amend § 68.12 by removing the word “Secretary” and adding the words “NIH

Director” in its place.

The purpose of this NPRM is to invite public comment concerning these proposed actions. We provide the following as public information.

Regulatory Impact Analysis

We have examined the impacts of this proposed rule under Executive Order (E.O.) 12866, Regulatory Planning and Review; E.O. 13563, Improving Regulation and Regulatory Review; E.O. 13132, Federalism; the Regulatory Flexibility Act (5 U.S.C. 601-612); and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563

E.O. 12866 and E.O. 13563 direct Federal agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity) for all significant regulatory actions. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year). Based on our analysis, we believe that the proposed rulemaking does not constitute an economically significant regulatory action.

Executive Order 13132

E.O. 13132, Federalism, requires Federal agencies to consult with State and local government officials in the development of regulatory policies with federalism implications. We reviewed the rule as required under the Order and determined that it does not have any federalism implications. This rule will not have effect on the States or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. For the purpose of this analysis, small entities include small business concerns as defined by the Small Business Administration

(SBA), usually businesses with fewer than 500 employees. Applicants who are eligible to apply for the loan repayment awards are individuals, not small entities. This rule will not create a significant impact on a significant number of small entities.

Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires Federal agencies to prepare a written statement which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal organizations, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation with base year of 1995) in any one year.”

The current inflation-adjusted statutory threshold is approximately \$156 million based on the Bureau of Labor Statistics inflation calculator. This rule will not result in a one-year expenditure that would meet or exceed that amount. Participation in the NIH loan repayment programs is voluntary and not mandated.

Paperwork Reduction Act

This proposed rule does not contain any new information collection requirements which are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). More specifically, § 68.6 is a reporting requirement, but the specifics of the burden are determined in the approved application forms used by the NIH Loan Repayment Programs and have been separately approved by OMB under OMB No. 0925-0361 (expires October 31, 2022). Additionally, §§ 68.3(c) and (e), 68.11(c), 68.14(c) and (d), and 68.16(a) are reporting requirements and/or recordkeeping requirements, but they also are covered under OMB No. 0925-0361.

Federal Assistance Listings

The Federal Assistance Listings numbered programs affected by this proposed rule are:

93.220 – NIH Intramural Loan Repayment Program

93.280 – NIH Extramural Loan Repayment Program

List of Subjects in 42 CFR Part 68

Health professions; ; Loan programs—health; Medical research.

For reasons presented in the preamble, the Department of Health and Human Services proposes to amend title 42 of the Code of Federal Regulations by revising Part 68, as set forth below.

PART 68—NATIONAL INSTITUTES OF HEALTH (NIH) LOAN REPAYMENT PROGRAMS (LRPs)

1. Revise the authority citation for part 68 to read as follows:

Authority: 42 U.S.C. 216, 42 U.S.C. 288-1, 42 U.S.C. 288-2.

2. Revise § 68.1 to read as follows:

§ 68.1 What are the scope and purpose of the NIH LRPs?

The regulations of this part apply to the award of educational loan payments authorized by sections 487A and 487B of the Public Health Service Act, as amended (42 U.S.C. 288-1, 42 U.S.C. 288-2). The purpose of these programs is to address the need for biomedical and behavioral researchers by providing an economic incentive to appropriately qualified health professionals who are engaged in qualifying research supported by domestic nonprofit funding or as employees of NIH. The NIH Loan Repayment Programs include two separate programs, the Intramural Loan Repayment Program (for NIH researchers) and the Extramural Loan Repayment Program (for non-NIH researchers).

(a) The Intramural LRP includes subcategories that focus on:

(1) General research, including a program for Accreditation Council for Graduate Medical Education (ACGME) Fellows;

(2) Research on acquired immune deficiency syndrome;

(3) Clinical research conducted by appropriately qualified health professionals who are from disadvantaged backgrounds; and

(4) An area of emerging scientific or workforce need.

(b) The Extramural LRP includes subcategories that focus on:

(1) Contraception or infertility research;

(2) Pediatric research, including pediatric pharmacological research;

(3) Minority health disparities research;

(4) Clinical research;

(5) Clinical research conducted by health professionals from disadvantaged backgrounds; and

(6) Research in emerging areas critical to human health.

3. Amend § 68.2 by:

a. Revising the definitions for “Debt threshold”, “Director”, “Educational expense”, “Extramural LRPs”, “Individual from disadvantaged background”, “Intramural LRPs”, “Loan repayment programs (LRPs)”, and “Loan Repayment Program contract”;

b. Removing the term “Nonprofit funding/support” and adding in its place a definition for “Nonprofit research funding/support”;

c. Revising the definitions of “Participant”, “Program eligibility date”, “Qualified Educational Loans and Interest/Debt”, “Reasonable educational and living expenses”, and “Repayable debt”;

d. Adding a definition for “Research in Emerging Areas Critical to Human Health”;

e. Removing the definition of “Secretary”; and

f. Revising the definition of “Waiver”.

The revisions and additions read as follows:

§ 68.2 Definitions.

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Debt threshold means the minimum amount of qualified educational debt an individual must have, on their program eligibility date, in order to be eligible for LRP benefits, as established by the NIH Director.

Director means the Director of the National Institutes of Health (NIH) or designee.

Educational expenses pertain to costs associated with the pursuit of the health professional's undergraduate, graduate, and health professional school's education, including the tuition expenses and other educational expenses such as living expenses, fees, books, supplies, educational equipment and materials, and laboratory expenses.

Extramural LRPs refers to those programs for which health professionals, who are not NIH employees and have program-specified degrees and domestic nonprofit support, are eligible to apply. The Extramural LRP includes subcategories that focus on:

- (1) Contraception or infertility research;
- (2) Pediatric research, including pediatric pharmacological research;
- (3) Minority health disparities research;
- (4) Clinical research;
- (5) Clinical research conducted by appropriately qualified health professionals who are from disadvantaged backgrounds; and
- (6) Research in emerging areas critical to human health.

* * * * *

Individual from disadvantaged background means:

- (1) Comes from an environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or
- (2) Comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for changes in the Consumer Price Index, and adjusted by the Secretary of Health and Human Services (HHS) for use in HHS programs. The Secretary periodically publishes these income levels in the Federal Register.

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Intramural LRPs refers to those programs for which applicants must be employed by the NIH. The Intramural LRP includes subcategories that focus on:

- (1) General research, including a program for Accreditation Council for Graduate Medical Education (ACGME) Fellows;
- (2) AIDS research;
- (3) Clinical research conducted by appropriately qualified health professionals from disadvantaged backgrounds; and
- (4) An area of emerging scientific or workforce need.

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Loan Repayment Programs (LRPs) refers to the NIH Loan Repayment Programs, including those authorized by sections 487A and 487B of the Act, as amended.

Loan Repayment Program contract refers to the agreement signed by an applicant and the NIH Director (or an appointed designee). Under such an agreement, an Intramural LRP applicant agrees to conduct qualified research as an NIH employee, and an Extramural LRP applicant agrees to conduct qualified research supported by domestic nonprofit funding, in exchange for repayment of the applicant's qualified educational loan(s) for a prescribed period.

* * * * *

Nonprofit research funding/support: applicants must conduct qualifying research supported by a domestic nonprofit foundation, nonprofit professional association, or other nonprofit institution (e.g., university), or a U.S. or other government agency (Federal, state or local). A domestic foundation, professional association, or institution is considered to be nonprofit if exempt from Federal tax under the provisions of Section 501 of the Internal Revenue Code (26 U.S.C. 501).

Participant means an individual whose application to any of the NIH LRPs has been approved and whose Program contract has been executed by the NIH Director or designee.

* * * * *

Program eligibility date means the date on which an individual's LRP contract is executed by the NIH Director or designee.

Qualified Educational Loans and Interest/Debt (see Educational Expenses) as established by

the NIH Director, include Government and commercial educational loans and interest for:

- (1) Undergraduate, graduate, and health professional school tuition expenses;
- (2) Other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and
- (3) Reasonable living expenses, including the cost of room and board, transportation and commuting costs, and other reasonable living expenses incurred.

Reasonable educational and living expenses means those educational and living expenses that are equal to or less than the sum of the school's estimated standard student budget for educational and living expenses for the degree program and for the year(s) during which the participant was enrolled in school. If there is no standard budget available from the school, or if the participant requests repayment for educational and living expenses that exceed the standard student budget, reasonableness of educational and living expenses incurred must be substantiated by additional contemporaneous documentation, as determined by the Secretary of HHS.

Repayable debt means the proportion, as established by the NIH Director, of an individual's total qualified educational debt that can be repaid by an NIH LRP.

Research in Emerging Areas Critical to Human Health refers to research designed to pursue major opportunities and gaps in biomedical research and expand research in emerging areas of human health. Emerging areas are considered new areas of biomedical and biobehavioral research where a critical mass of capability and expertise is still emerging across the biomedical and biobehavioral research community.

* * * * *

Waiver means a waiver of the service obligation granted by the NIH Director when compliance by the participant is impossible or would involve extreme hardship, or where enforcement with respect to the individual would be unconscionable. (See Breach of contract.)

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4. Amend § 68.5 by revising paragraph (d) to read as follows:

§ 68.5 Who is ineligible to participate?

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(d) For Extramural LRPs only: Individuals who receive any salary support or participate in research that receives funding support from a for-profit institution or organization, or Federal Government employees working more than 20 hours per week;

* * * * *

5. Revise § 68.6 to read as follows:

§ 68.6 How do individuals apply to participate in the NIH LRPs?

An application for participation in an NIH LRP shall be submitted to the NIH, which is responsible for the Program's administration, in such form and manner as the NIH Director prescribes.

6. Amend § 68.7 by revising paragraph (d)(2)(iii) to read as follows:

§ 68.7 How are applicants selected to participate in the NIH LRPs?

* * * * *

(d) * * *

(2) * * *

(iii) For the Health Disparities Research subcategory, at least 50 percent of the contracts are required by statute to be for appropriately qualified health professionals who are members of a health disparity population.

7. Amend § 68.8 by revising paragraph (a) to read as follows:

§ 68.8 What do the NIH LRPs provide to participants?

(a) Loan repayments: For each year of the applicable service period the individual agrees to

serve, the NIH may pay up to \$50,000 per year of a participant's repayable debt.

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8. Revise § 68.12 to read as follows:

§ 68.12 How does an individual receive loan repayments beyond the initial applicable contract period?

An individual may apply for a competitive extension contract for at least a one-year period if the individual is engaged in qualifying research and satisfies the eligibility requirements specified under §§ 68.3 and 68.4 of this part for the extension period and has remaining repayable debt as established by the NIH Director.

Xavier Becerra,

Secretary,

Health and Human Services.

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